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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,504	07/08/2005	Sabine Pfeffer	TX/4-32852A	4096
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NOVARTIS				
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ONE HEALTH PLAZA 104/3				
EAST HANOVER, NJ 07936-1080				
EXAMINER				
GALLIS, DAVID E				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
06/23/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/541,504

**Applicant(s)**

PFEFFER ET AL.

**Examiner**

DAVID E. GALLIS

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6 and 11-15 is/are allowed.
- 6) ☒ Claim(s) 7-10 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 7/8/05, 12/6/05, and 1/3/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1 through 16 are pending. Claims 1 through 6, and 9 have been amended. Claims 12 through 16 have been newly entered. Applicants' claim to foreign priority from application UNITED KINGDOM 0301259.8 filed January 20, 2003 is acknowledged.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9, 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haeberlin et al. (WO 97/38689, October 23, 1997).

4. Claims 9 is drawn to a pharmaceutical composition in the form of tablets comprising crystals of an acicular drug substance with an aspect ration of 10:1 to 1:1 and/or a bulk density above 200 kg/m<sup>3</sup> for use as a pharmaceutical. Claim 10 is drawn to crystals of mycophenolic acid or mycophenolate salt specifically, with an aspect ration of 10:1 to 1:1 and/or a bulk density above 200 kg/m<sup>3</sup> for use as a pharmaceutical. Claim 16 is drawn to a pharmaceutical composition in the form of tablets, comprising crystals of a process for recrystallising an acicular drug substance comprising suspending said crystals in a solvent system having an effect on the crystal habit and subjecting said suspension to a temperature oscillation.

5. Claims 9, 10, and 16 are obvious over Haerberlin et al. for the following reasons. Haerberlin et al. teach a mycophenolate sodium salt in a pharmaceutical composition (see page 2, lines 5 through 15; page 3, lines 1 through 6). The mycophenolate sodium salt is an acicular drug substance. While the instant specification teaches a modified crystal habit for an acicular drug substance (mycophenolate salt specifically), there is no evidence that the modified crystalline morphology possesses any different pharmacological properties than that of the salt taught by Haerberlin et al.. Therefore the acicular drug substance (mycophenolate) of the pharmaceutical compositions of the instant claims and that taught by Haerberlin are considered to be the same drug substances, and thus the same compositions.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7 through 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 7, the phrase "and/or" renders the claim(s) indefinite because the claim recites elements in both the inclusive and in the alternative, thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

9. Claims 8 through 10 are rejected due to their dependency on rejected base claim 7.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis  
Patent Examiner  
/ Bernard Dentz/  
Primary Examiner, Art Unit 1625